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Voluntary - Public

Date: 5/12/2010

GAIN Report Number:

China - Peoples Republic of

Post: Beijing

Food Additive Registration

Report Categories:

FAIRS Subject Report

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Report Highlights:

On March 10, 2010, China's Ministry of Health published "Order No. 73: Measures for Administration of New Food Additives." These measures were "formulated for the purpose of reinforcing administration of new food additives in accordance with the *Food Safety Law*." This measure went into force on March 10, the date of its publication.

General Information: Summary

On March 10, 2010, China's Ministry of Health published "Order No. 73: Measures for Administration of New Food Additives." These measures were "formulated for the purpose of reinforcing administration of new food additives in accordance with the *Food Safety Law*." The measure is meant as a general guideline for how the Ministry of Health deals with new food additive applications. This measure went into force on March 10, the date of its publication.

This report contains an UNOFFICIAL translation of this measure.

BEGIN TRANSLATION

Order No. 73 of the Ministry of Health of the People's Republic of China

The *Measures for Administration of New Food Additives*, adopted by the Ministry of Health at its executive meeting on 15 March 2010, are hereby promulgated and shall come into force on the date of promulgation.

Minister Chen Zhu

30 March 2010

Article 1 These Measures are formulated for the purpose of reinforcing administration of new food additives in accordance with the *Food Safety Law of the People's Republic of China* and the *Regulations for Implementation of Food Safety Law*.

Article 2 New food additives refer to:

- (1) food additives that are not included in the national food safety standards;
 - (2) food additives that are not included in the public announcement of permitted use issued by the Ministry of Health;
- and
- (3) food additives whose scope of use or dosage is increased.

Article 3 Food additives shall be technically necessary and proven safety and reliable through risk assessment.

Article 4 Food additives shall be used:

- (1) without concealing deterioration of food;
- (2) without concealing any quality defect of the food itself or its processing;
- (3) not for the purpose of adulteration or counterfeiting;
- (4) without compromising nutritive value of the food itself;
- (5) deliver the expected effects at the lowest level of addition; and
- (6) if such additives are processing agent for the food industry, removed prior to completion of the finished product, unless any residual is permitted.

Article 5 The Ministry of Health shall take charge of reviewing and permitting new food additives and developing the technical evaluation and review specifications for new food additives.

Article 6 Entities and individuals that apply for production, operation, use or import of new food additives (the "Applicants") shall file an application for the permit of new food additives and submit the following materials:

- (1) Generic name, functions, dosage and scope of use of additives;

- (2) Materials or documents demonstrating technical necessity and efficiency of additives;
- (3) Quality requirements, manufacturing process and testing methods of food additives, and testing methods of such additives in food or relevant explanations;
- (4) Safety assessment data, including raw materials or sources, chemical constitution and physical properties, manufacturing process, toxicological safety assessment data or test report and quality test report;
- (5) Label, specifications and sample of food additives; and
- (6) Data on permission of manufacture and use granted by other countries or regions or international organizations and other data that may help in safety assessment.

Any application for increase in the scope of use or dosage of food additives may be exempt from provision of materials set out in Item (4) above, unless additional data are required during technical review.

Article 7 Any Applicant for the initial import of new food additives shall submit the following materials in addition to those set out in Article 6:

- (1) Supporting documents permitting manufacture or sale of such additives in the exporting country or region that are issued by relevant authority or agency thereof; and
- (2) Supporting documents examining or certifying the manufacturer that are issued by relevant agency or organization in the country or region where the manufacturer is located.

Article 8 Applicants shall provide true materials that reflect the facts, be responsible for the authenticity of application materials and assume any legal consequences.

Article 9 Applicants shall make a statement that no business secrets are involved and disclose to the public is permitted in the materials set out in Items (1), (2) and (3) of the first paragraph of Article 6.

The technical necessity and efficiency of new food additives shall be determined in consultation with the public, government agencies in charge: Administration for Quality, Supervision, Inspection and Quarantine, State Administration for Industry and Commerce, the State Food and Drug Administration, Ministry for Industry, Information and Technology, and relevant trade organizations.

A public hearing may be held to solicit opinions in the case of any major difference in opinions or involvement of major interests.

Opinions collected may be used as a reference point for technical review.

Article 10 The Ministry of Health shall, within sixty days of receiving an application, organize experts in medicine, agriculture, food, nutrition and process to conduct a review of the technical necessity and safety assessment data of new food additives and draw a conclusion of the technical review. Where any additional data are required for technical review, the Applicant shall be notified thereof and provide such additional data as required on a timely basis.

Where necessary, experts may be organized to examine and assess the research and manufacture sites of new food additives.

Where relevant data and test results shall be verified or inspected, the inspection items, batches and methods shall be notified to the Applicant. The safety verification and inspection shall be conducted by certified inspection agencies. The inspection methods shall be verified first where no national standards on food safety inspection methods are available.

Article 11 The administrative license of a new food additive shall be subject to relevant provisions of the *Administrative License Law of the People's Republic of China* and the *Measures for Administration of Hygienic Administrative License*.

Article 12 Based on results of technical review, the Ministry of Health will included new food additives that demonstrate technical necessity and compliance with food safety requirements in the list of permitted food additives and make an announcement thereof.

In the case of lack of technical necessity or non-compliance with food safety requirements, the permit shall not be granted and a written statement of reasons shall be provided.

Any non-food chemical substance or any other substance adverse to human health substance that may be added to the

food shall be subject to Article 49 of the *Regulations for Implementation of Food Safety Law*.

Article 13 The Ministry of Health shall, based on the assessment results of technical necessity and food safety risks, develop and publish national food safety standards on the type, scope of use and dosage of food additives permitted by public announcement.

Article 14 The Ministry of Health shall re-assess food additives in a timely manner in any of the following circumstances:

- (1) Research findings or any evidence demonstrates any possible problem in the safety of food additives; or
- (2) Technical necessity no longer exists.

Where the re-assessment finds non-compliance with food safety requirements, the Ministry of Health may make a public announcement revoking approved food additives or alter their scope of use or dosage.

Article 15 These Measures shall enter into force on the date of issuance. The *Measures for Hygienic Administration of Food Additives* issued on 28 March 2002 shall be repealed at the same time.

END TRANSLATION